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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/747,371	12/21/2000	Kurt C. Gish	A-69028/DJB/JJD	8631

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EXAMINER	
JOHANNSEN, DIANA B	
ART UNIT	**PAPER NUMBER**
1634	7

DATE MAILED: 03/27/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/747,371	GISH ET AL.	
	Examiner	Art Unit	
	Diana Johannsen	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-31 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-31 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *Detailed Action* .

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-2, drawn to methods of screening drug candidates, classified in class 435, subclasses 6 and 7.1.

II. Claim 3, drawn to methods of screening for agents that bind a protein, classified in class 435, subclass 7.1.

III. Claim 4, drawn to methods of screening for agents that modulate protein activity, classified in class 435, subclass 7.1.

IV. Claims 5-6, drawn to methods of evaluate the effect of a drug on a patient, classified in class 424, subclass 9.2 and class 435, subclasses 6 and 7.1.

V. Claim 7, drawn to methods of diagnosing cancer, classified in class 435, subclasses 6 and 7.23.

VI. Claims 8-13, drawn to antibodies, classified in class 530, subclass 387.1.

VII. Claims 14-15, drawn to methods of screening for binding inhibitors, classified in class 435, subclass 7.1.

VIII. Claims 16-20, drawn to methods of inhibiting protein activity and treating cancer with antibodies, classified in class 424, subclass 138.1.

IX. Claims 21-26, drawn to methods of treating cancer by delivering therapeutics using an antibody, classified in class 424, subclass 155.1.

X. Claim 27, drawn to methods of inhibiting cancer with antisense nucleic acids, classified in class 514, subclass 44.

XI. Claim 28, drawn to a biochip, classified in class 435, subclass 287.2.

XII. Claim 29, drawn to methods of eliciting an immune response with a protein, classified in class 514, subclass 2.

XIII. Claim 30, drawn to methods of eliciting an immune response with a nucleic acid, classified in class 514, subclass 44.

XIV. Claim 31, drawn to methods of determining cancer prognosis, classified in class 435, subclass 7.1.

It is first noted that applicant has presented several claims that encompass methods of detecting nucleic acids as well as methods of detecting proteins. Such claims are improper as nucleic acids and polypeptides are structurally and functionally distinct molecules. Nucleic acids are composed of nucleotides and function in, e.g., methods of hybridization, while proteins are composed of amino acids and function in, e.g., enzymatic methods or binding assays. Further, the method steps and reagents required to detect nucleic acids are separate and distinct from those required to detect proteins. Thus, a reference against one method encompassed by these claims would not be a reference against the other. Accordingly, as Groups I, IV, and V consist of claims to methods in which nucleic acids and proteins are improperly joined, **upon election of any of these groups, applicants must further elect either nucleic acids**

or polypeptides. See also *Ex parte Markush*, 1925 C.D. 126 and *In re Weber* 198 USPQ 328.

2. The inventions are distinct, each from the other because of the following reasons:

Inventions I, II, III, IV, V, VII, XII and XIV are patentably distinct methods. While each of the methods may employ proteins, the methods are patentably distinct because the have different objectives and require different process steps. Invention I requires a step of adding a "drug candidate" to achieve the objective of screening drug candidates. Invention II requires a step of detecting binding between a protein and a "candidate bioactive agent" to achieve the objective of screening for binding. Invention III requires a step of detecting the effect of an agent on protein activity to achieve the objective of screening for modulated activity. Invention IV requires a step of administering a drug to a patient to achieve the objective of evaluating drug effects. Invention V requires a step of detecting gene expression to achieve the objective of diagnosing cancer. Invention VII requires a step of combining a protein, a candidate bioactive agent and an antibody to achieve the objective of screening for inhibition of binding. Invention XII requires a step of administering a protein to a patient to achieve the objective of eliciting an immune response. Invention XIV requires a step of determining protein levels to achieve the objective of determining cancer prognosis.

Inventions I, II, III, IV, V, VII, VIII, IX, XII, and XIV are patentably distinct methods. While each of the methods may employ antibodies, the methods are patentably distinct because the have different objectives and require different process steps. Invention I requires a step of adding a "drug candidate" to achieve the objective of screening drug

candidates. Invention II requires a step of detecting binding between a protein and a "candidate bioactive agent" to achieve the objective of screening for binding. Invention III requires a step of detecting the effect of an agent on protein activity to achieve the objective of screening for modulated activity. Invention IV requires a step of administering a drug to a patient to achieve the objective of evaluating drug effects. Invention V requires a step of detecting gene expression to achieve the objective of diagnosing cancer. Invention VII requires a step of combining a protein, a candidate bioactive agent and an antibody to achieve the objective of screening for inhibition of binding. Invention VIII requires a step of administering an antibody to a cell to achieve the objective of inhibiting cancer. Invention IX requires a step of exposing tissue to an antibody or administering an antibody to an individual to achieve the objective of treatment. Invention XII requires a step of administering a protein to a patient to achieve the objective of eliciting an immune response. Invention XIV requires a step of determining protein levels to achieve the objective of determining cancer prognosis.

Inventions I, IV, V, X, and XIII are patentably distinct methods. While each of the methods may employ nucleic acids, the methods are patentably distinct because the have different objectives and require different process steps. Invention I requires a step of adding a "drug candidate" to achieve the objective of screening drug candidates. Invention IV requires a step of administering a drug to a patient to achieve the objective of evaluating drug effects. Invention V requires a step of detecting gene expression to achieve the objective of diagnosing cancer. Invention X requires a step of administering antisense molecules to achieve the objective of inhibiting cancer. Invention XIII requires

a step of administering nucleic acids encoding a protein or fragment thereof to achieve the objective of eliciting an immune response.

Inventions X and XIII are unrelated to Inventions II, III, VII, IX, XII, and XIV. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to materially distinct methods that require the use of different reagents, have different process steps and have distinct objectives. Invention X requires the use of nucleic acids, which nucleic acids are administered to a cell to achieve the objective of inhibiting cancer. Invention XIII requires the use of nucleic acids, which nucleic acids are administered to an individual to achieve the objective of eliciting an immune response. Each of inventions II, III, VII, VIII, IX, XII, and XIV require the use of proteins and/or antibodies. Invention II requires a step of detecting binding between a protein and a "candidate bioactive agent" to achieve the objective of screening for binding. Invention III requires a step of detecting the effect of an agent on protein activity to achieve the objective of screening for modulated activity. Invention VII requires a step of combining a protein, a candidate bioactive agent and an antibody to achieve the objective of screening for inhibition of binding. Invention VIII requires a step of administering an antibody to a cell to achieve the objective of inhibiting cancer. Invention IX requires a step of exposing tissue to an antibody or administering an antibody to an individual to achieve the objective of treatment. Invention XII requires a step of administering a protein to a patient to achieve the objective of eliciting an

immune response. Invention XIV requires a step of determining protein levels to achieve the objective of determining cancer prognosis.

Inventions VI and XI are patentably distinct products having different structures and functions. The antibodies of Invention VI are composed of amino acids, have a particular tertiary structure, and have particular binding properties. The biochip of group XI is an array of nucleic acids, which are composed of nucleotides, in combination with other materials supporting and providing a particular structure to those nucleic acids; said biochip is employed in methods such as screening. Accordingly, Inventions VI and XI are distinct from one another.

Inventions VI and II-IV, VI and V, VI and VII-IX, and VI and XIV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the antibodies of invention VI may be used in a materially different process, such as methods of protein purification.

Inventions XI and I, XI and IV, and XI and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant

case, the biochip of Invention XI may be used in a materially different process, such as methods of identifying novel homologues of BCO2.

Inventions XI and II-III, XI and VII-X, and XI and XII-XIV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the biochip of Invention XI is not disclosed as capable of use in the methods of Inventions II-III, VII-X, and XII-XIV, and function in methods that are materially distinct and have different effects from those of Inventions II-III, VII-X, and XII-XIV, such as, e.g., methods of screening for novel gene homologues.

Inventions VI and X and VI and XII-XIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the antibodies of Invention VI are not disclosed as capable of use in the methods of Inventions X and XII-XIII, and function in methods that are materially distinct and have different effects from those of Inventions X and XII-XIII, such as, e.g., methods of protein purification.

3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and recognized divergent subject matter, and because Inventions I-XIV require different searches that are not co-extensive, examination of these distinct inventions would pose

a serious burden on the examiner and therefore restriction for examination purposes as indicated is proper.

4. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Diana B. Johannsen whose telephone number is 703/305-0761. The examiner can normally be reached on Monday-Friday, 7:30 am-4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached on 703/308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are 703/872-9306 for regular communications and 703/872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703/308-0196.

Diana B. Johannsen
March 23, 2002

W. Gary Jones
Supervisory Patent Examiner
Technology Center 1600